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10/591,451

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Ernestine Lee

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05/10/2010

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP

901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

LEAVITT, MARIA GOMEZ

ART UNIT

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1633

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-----------------------------------|--|
| Office Action Summary | Application No. 10/591,451 | Applicant(s) LEE ET AL. | |
| | Examiner MARIA LEAVITT | Art Unit 1633 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 5, 6, 8, 13, 18, 23, 30-32, 34-36 and 41 is/are pending in the application.
- 4a) Of the above claim(s) 35 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 6, 8, 13, 18, 23, 30- 32, 34-36 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 5, 6, 8, 13, 18, 23, 30-32, 34-36 and 41 are currently pending. Claims 1, 8, 35 and 36 have been amended; claims 16, 17, 44, 49, 52, 53, 55, 64, 70, 74, 76, 78 and 80 have been cancelled by Applicants' amendment filed on 03-02-2010. Claims 35 and 36 were previously withdrawn from consideration as being drawn to a non-elected invention pursuant to 37 CFR 1.14(b), there being no allowable generic or linking claim. Election was made with traverse in Applicants' reply filed on 09-03-2009.

Response to Applicants' arguments

At page 6 of the remarks filed on 03-02-2010, Applicants request rejoining of withdrawn claims 35 and 36 according to the policy established in M.P.E.P. § 821.04. The examiner notes that because the product claims 1 and 8 are not allowable, nonelected process claims 35 and 36 that depend from or otherwise include all the limitations of the patentable product will be not will be rejoined for search and examination in the current office action. See MPEP § 821.04 and § 821.04(a)

Therefore, claims 1, 5, 6, 8, 13, 18, 23, 30-32, 34 and 41 are currently under examination to which the following grounds of rejection are applicable.

Response to arguments

Withdrawn objections/rejections in response to Applicants' arguments or amendments:

35 USC 101-non-statutory subject matter

Art Unit: 1633

In view of Applicants' amendment of claims 1 and 8 to recite the limitation "isolated", rejection of claims 1, 5, 6, 8, 13, 16, 17, 18, 23, 30-32, 34, 41 and 80 under 35 USC §101 has been withdrawn.

Applicants' arguments are moot in view of the withdrawn rejection.

Claim Rejections - 35 USC § 112, First Paragraph-written description

In view of Applicants' amendment of claims 1 and 8, rejection of claims 1, 5, 6, 8, 13, 18, 23, 30-32, 34 and 41 under 35 U.S.C. 112, first paragraph, written description, has been withdrawn.

Applicants' arguments are moot in view of the withdrawn rejection.

Claim Rejections - 35 USC § 112, First Paragraph-Scope of enablement

In view of Applicants' amendment of claims 1 and 8, rejection of claims 1, 5, 6, 8, 13, 18, 23, 30-32, 34 and 41 under 35 U.S.C. 112, first paragraph, enablement, has been withdrawn.

Applicants' arguments are moot in view of the withdrawn rejection.

Objections/rejections maintained in response to Applicant arguments or amendments:

Claim Rejections - 35 USC § 112

Claim 1, 5, 6, 18, 23, 30, 32 and 34 remain rejected under 35 U.S.C. 112, second paragraph, because of the recitation of, "a first polynucleotide that comprises a nucleotide sequence chosen from a polynucleotide encoding a polypeptide comprising amino acid sequence SEQ ID NO:215". The term "chosen" refers to the election of two or more choices. It is unclear what the term "chosen" refers to in the context of this sentence as there is only one choice to

Art Unit: 1633

elect from, i.e., a polypeptide comprising the amino acid sequence SEQ ID NO: 215.

Appropriate correction is required.

Claims 5, 6, 18, 23, 30, 32 and 34 are indefinite insofar as they depend directly or indirectly from claim 1.

Claim Rejections - 35 USC § 102(b)

To the extent that claim 1 is broadly but reasonably interpreted as comprising an isolated nucleic acid molecule comprising a first polynucleotide that comprises a polynucleotide sequence encoding a polypeptide of SEQ ID NO:215 which encompass: (1) nucleic acids that encode the full-length of SEQ ID NO:215 or (2) any polypeptide portion of SEQ ID NO: 215, reading on isolated nucleic acid fragments encoding portions of SEQ ID NO: 215, the following rejection stands.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 6, 8, 13, 18, 23, 30-32, 34 and 41 remain rejected under 35 USC. 102(b) as being anticipated by Rosen et al., (WO 00/55200 International Publication Date 21 September 2000; See SCORE Search Results Details for Application 10591451 and Search Result 20091110_135148_us-10-591-451-215.rag. Result 2)

Response to Applicants' arguments' as they relate to rejection of claims 1, 5, 6, 8, 13, 18, 23, 30-32, 34 and 41 under 35 USC. 102(b)

Art Unit: 1633

At page 8 of Remarks, Applicants essentially argue that the sequence from WO 00/55200 only shows 43.4% identity with SEQ ID NO: 215, therefore, it does not encompass all of the elements of independent claims 1 and 8. Such is not persuasive.

Claim 1 is broadly but reasonably interpreted as comprising an isolated nucleic acid molecule comprising a first polynucleotide that comprises a polynucleotide sequence encoding a polypeptide of SEQ ID NO: 215 which encompass: (1) nucleic acids that encode the full-length of SEQ ID NO:215 or (2) any polypeptide portion of SEQ ID NO: 215, reading on isolated nucleic acid fragments (e.g., the “ATGGGGTTTCATCATGTTGGCCAG” sequence encoding for “MGFHHVGQ” of SEQ ID NO:215. Claim 8 is interpreted as comprising an isolated polypeptide comprising the full length of SEQ ID NO: 215 or (2) any polypeptide portion of SEQ ID NO: 215, e.g., “MGFHHVGQ”.

New grounds of objection/rejection

New claim objection

Claim 1 is objected to because of the following informalities: the phrase “comprising amino acid sequence” in lines 3-4 requires the use of an indefinite article “a” or a definite article “the” inserted in front of the phrase. For example, “comprising an amino acid sequence” or “comprising the amino acid sequence”. Appropriate correction is required.

Likewise, claim 8 is objected to because of the following informalities: the phrase “first amino acid” requires the use of an indefinite article “a” or a definite article “the” in front of the phrase. Appropriate correction is required.

Art Unit: 1633

Claim 6 is objected to because of the following informalities. Claim 6 recites “the second polynucleotide comprises a second nucleotide sequence encoding a secretory leader”. There is not a reference to a first nucleotide sequence for the second polynucleotide comprised in the second nucleotide sequence. Appropriate correction is required.

Claims 30, 31 and 34 are objected to because of the following informalities. Each of these claims refers to the product (nucleic acid molecule, polypeptide or host cell) of a preceding claim by use of an indefinite article “a”. The use of an indefinite article in this context is grammatically incorrect, i.e. the definite article --the-- should be used in this context. For example, “a” (claim 34) “recombinant host cell of claim 23...” should be --the-- “recombinant host cell of claim 23...”. Appropriate correction is required.

Claims 6 and 13 are objected to because of the following informalities. A polynucleotide sequence classically encodes a polypeptide sequence. It is unclear how the second polynucleotide encodes a secretory leader that is not a sequence or polypeptide. Appropriate correction is required.

Claim Rejections - 35 USC § 102(b)

To the extent that claims 1 and 8 broadly encompass an isolated nucleic acid molecule and corresponding polypeptides comprising the full length of SEQ ID NO: 215 with or without additional nucleotides/amino acids at either or both ends, the following rejection applies.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of

Art Unit: 1633

application for patent in the United States.

Claims 1 and 8 are newly rejected under 35 USC. 102(b) as being anticipated by Wang et al., (U.S .Patent Application No. 10/301,480; priority date 08/2001, SCORE Search Results Details for Application 10591451 and Search Result 20091120_115703_us-10-591-451-215.rni. Result 3,). **This is a new rejection necessitated by amendment of the claims in the response filed 03/02/2010.**

Wang et al., teaches an isolated nucleotide sequence of SEQ ID NO: 87969 having 988 nucleotides and having an amino acid sequence homology of 100% to the amino acid sequence of SEQ ID NO: 215, the 79-residue amino acid sequence of the invention (See, Search Result 20091120_115703_us-10-591-451-215.rni. pg 5, Result 3). Thus by teaching an isolated nucleotide sequences comprising the claimed isolated nucleotide sequence encoding the amino acid sequence of SEQ ID NO:215 and additional nucleotides/amino acids at both ends, Wang anticipates the instant invention.

References made of record in a PTO-892 Form to complete the record

SCORE Search Results Details for Application 10591451 and Search Result 20091120_115702_us-10-591-451-215.rge. Results 1-5

Conclusion

Claims 1, 5, 6, 8, 13, 18, 23, 30-32, 34 and 41 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1633

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/591,451

Page 9

Art Unit: 1633

/Maria Leavitt/

Maria Leavitt

Primary Examiner, Art Unit 1633